NHANES 2001–2002 Data Release
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Documentation for Laboratory Results

Laboratory 10AM – Glucose, Insulin, and C-Peptide

(1) Documentation File Date – April 1, 2005

(2) Documentation File Name – Laboratory 10AM – Glucose, Insulin, and C-Peptide

(3) Survey Years Included in this File Release – 2001–2002

(4) Component Description

Diabetes mellitus was assessed by measures of plasma glucose, serum insulin, and serum C-peptide in participants aged 12 years and over in the morning examination session only. Glycohemoglobin measures were available for a full sample.

Diabetes is a leading cause of disease and death in the United States. Eight million Americans are known to have diabetes, and an equal number have undiagnosed diabetes. In 1993, nearly 18 percent of all deaths for persons over the age of 25 were among people with diabetes. The prevalence of diabetes and overweight (one of the major risk factors for diabetes) continue to increase. Substantial new efforts to prevent or control diabetes have begun, including the Diabetes Prevention Trial and the National Diabetes Education Program.

Information on the prevalence of diabetes disease, especially in its early stages, and associated risk factors will be used to help develop early intervention and prevention programs for the disabling consequences of this condition. Specifically, the diabetes disease examination will provide population data to: 1) determine a national estimate of diabetes disease prevalence (diagnosed and undiagnosed), including those at high risk for the late complications of the disease (i.e., ulceration and amputation); 2) identify the risk factors of diabetes disease; 3) permit a national cohort to be established for follow-up studies of this condition; and 4) provide critical information to clinicians and public health officials for the development of preventive care and community-based interventions.

(5) Sample Description

5.1 Eligible Sample

Participants aged 12 years and older who were examined in the morning session were tested. Fasting weights are available for sample persons fasting at least 8 hours or more but less than 24 hours.

(6) Description of the Laboratory Methodology

6.1 Glucose

The enzyme hexokinase (HK) catalyzes the reaction between glucose and adenosine triphosphate (ATP) to form glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). In the presence of nicotinamide adenine dinucleotide (NAD), G-6-P is oxidized by the enzyme glucose-6-phosphate dehydrogenase (G-6-PD) to 6-phosphogluconate and reduced nicotinamide adenine dinucleotide (NADH). The increase in NADH concentration is directly proportional to the glucose concentration and can be measured spectrophotometrically at 340 nm.

6.2 Insulin

Insulin radioimmunoassay (RIA) is a double-antibody batch method. Insulin in the specimen competes with a fixed amount of ^{125}I-labelled insulin for the binding sites of the specific insulin antibodies. Bound and free insulin are separated by adding a second antibody, centrifuging, and decanting. The radioactivity in the pellet is then measured. The radioactivity is inversely proportional to the quantity of insulin in the specimen.

6.3 C-Peptide

C-peptide radioimmunoassay (RIA) is a competitive assay where ^{125}I-labelled C-peptide competes with C-peptide in the specimen for antibody sites. Bound and free C-peptide is separated by adding a second PEG-accelerated double antibody. The antibody-bound fraction is precipitated and counted. The radioactivity is inversely proportional to the quantity of insulin in the specimen.

(7) Laboratory Quality Control and Monitoring

The NHANES quality control and quality assurance protocols (QA/QC) meet the 1988 Clinical Laboratory Improvement Act mandates. Detailed quality control and quality assurance instructions are discussed in the NHANES Laboratory/Medical Technologists Procedures Manual (LPM). Read the LABDOC file for detailed QA/QC protocols.

(8) Data Processing and Editing

Blood specimens were processed, stored and shipped to University of Missouri-Columbia, Columbia, Missouri for analysis. Detailed specimen collection and processing instructions are discussed in the LPM. Read the LABDOC file for detailed data processing and editing protocols. The analytical methods are described in the Description of the Laboratory Methodology section.

(9) Data Access

All data are publicly available.

(10) Analytic Notes for Data Users

10.1 NHANES 2001–2002 Laboratory Data

The analysis of NHANES 2001–2002 laboratory data must be conducted with the key survey design and basic demographic variables. The NHANES 2001–2002 Household Questionnaire Data Files contain demographic data, health indicators, and other related information collected during household interviews. They also contain all survey design variables for these age groups. The phlebotomy file includes auxiliary information such as the conditions precluding venipuncture. The household questionnaire and phlebotomy files may be linked to the laboratory data file using the unique survey participant identifier SEQN.

10.2 LBXGLU and LBXGLUSI, Plasma glucose; LBXCP and LBXCPSI, C-peptide; LBXIN and LBXINSI, Insulin

Plasma glucose, serum C-peptide and insulin were measured by the Diabetes Diagnostic Laboratory at the University of Missouri-Columbia on participants aged 12 years and older in the morning examination session only.

The Laboratory 10 Data File which contains laboratory test results for glucose (LBXGLU) was measured using the reference analytic method. However, the Lab 40 biochemistry profiles also included measurements of this analyte. These serum glucose values (LBXSGL) reported in Lab 40 release should not be used to determine undiagnosed diabetes or prediabetes. Instead, plasma glucose values (LBXGLU) should be used based on the reference analytic method of this analyte. Use the special weights included in this data file when analyzing data.

10.3 Fasting Weights: WTSFA4YR

The analyst is strongly encouraged to use the 4-year MEC-examined fasting weights (WTSFA4YR) to analyze 1999-2002 plasma glucose, serum C-peptide, and insulin. Non-zero fasting weights were generated for sample persons 12 years and older, fasting at least 8 hours or more but less than 24 hours and examined in the morning session. In addition, these sample persons were never told by a healthcare provider that they had diabetes (DIQ010 not equal to1) and had non-missing glucose values or the healthcare provider said they had diabetes (DIQ010=1). The 2-year fasting weights for 2001–2002 will be released in the Spring of 2005. See Analytic Guidelines (at http://www.cdc.gov/nchs/data/nhanes/nhanes_general_guidelines_june_04.pdf).

The dataset includes 2-year and 4-year subsample weights. The 4-year weights should be used if these 2001–2002 data are combined with 1999–2000 data. The 1999–2000 data files have been updated to include the subsample 4-year weights. The recommended procedure for variance estimation requires use of stratum and PSU variables (SDMVSTRA and SDMVPSU, respectively), which are included in the demographic data file for each data release. For further information, see the NHANES Analytic Guidelines, June 2004 version at: http://www.cdc.gov/nchs/data/nhanes/nhanes_general_guidelines_june_04.pdf.

(11) References

N/A